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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/729,450

Filing Date: December 05, 2003

Appellant(s): KHOO ET AL.

Wendell Ray Guffrey
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 28 August 2006 appealing from the Office action mailed 27 January 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The examiner relies upon Shields, Jr. et al (US Patent 6,156,355), Wadsworth et al (US Patent 6,737,089), Klimberg et al (*Arch Surg.* 1990), Chandler (*In Practice*, 2002) and Taber's Cyclopedic Medical Dictionary, 1997, F.A. Davis Company, 18th edition, pages 535-536.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(a) The rejection of claims 1-15, 17 and 19 under 35 U.S.C. 103(a) over Shields, Jr et al, in view of Wadsworth et al and Klimberg et al

Claims 1-15, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shields, Jr. et al (US Patent 6,156,355), in view of Wadsworth et al (US Patent 6,737,089) and Klimberg et al (*Arch Surg.*, 1990).

Applicants claim 1 is directed to a composition suitable for oral ingestion by a mammal, comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3-fatty acid(s).

Dependent claims 2, 3 and 15 further define the mammal for which the composition must be suitable.

Dependent claims 4-13 further limit the quantity of each of the claimed components in the composition.

Applicants claim 14 is directed to a method for managing diarrhea in a mammal having GI tract inflammation, comprising orally administering the composition of claim 1. Dependent claim 17 further limits the type of mammal. Applicants claim 19 is directed to a method for managing diarrhea in a non-canine mammal, comprising orally administering to the mammal a composition comprising from about 0.1% to about 5% by weight glutamine, from about 0.5% to about 20% by weight fermentable fiber(s), from about 0.1% to about 3% by weight antioxidant(s), and from about 0.1% to about 3% by weight omega-3 fatty acid(s).

Shields, Jr. et al teach a dog food composition, 'The Herding Diet' which comprises fermentable fibers, in the amount of 4.0%; omega-3 fatty acids, in the amount of 0.2%; antioxidants; and glutamine (See Shields, Jr. et al, col. 9, ln 48-51; col. 11, ln 25-38 & 53-54; col. 12, ln 11-15; col. 23, ln 4-14 & 'Analysis'). The 'Herding Diet' is specially formulated for dogs that are prone to chronic GI inflammation and diarrhea; it is designed to be fed to dogs as a means of controlling GI inflammation and diarrhea (See Shields, Jr. et al, col. 11, ln 18-28). Shields, Jr. et al teach that the glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See Shields, Jr. et al, col. 12, ln 11-22); however, they do not disclose a precise amount of glutamine to include in the diet.

Wadsworth et al and Klimberg et al both provide similar teachings on the benefits of glutamine on intestinal health during times of gastrointestinal stress (such as bouts of diarrhea). Wadsworth et al teach glutamine, 5-10% wt, as an additive to animals' diets, specifically dog and cat diets, can provide improved digestive system support (See Wadsworth et al, col. 7, ln 51-60 and col. 13, ln 34-49 (Example 4)). Klimberg et al teach adding glutamine, 3% wt, to diets of rats suffering gastrointestinal distress from abdominal radiation, resulted in diminished bloody diarrhea and reduced the incidence of bowel perforation (See Klimberg et al, Pg 1040, col. 2- Pg. 1041, col. 2).

It would therefore have been obvious to the person of ordinary skill in the art at the time the invention was made to use the amounts of glutamine specified by either Wadsworth et al or Klimberg et al (5-10% and 3%, respectively) in the diet disclosed by Shields, Jr. et al. Shields, Jr. et al already teach using glutamine in the 'Herding Diet' in order to treat stressed GI tracts, however because they do not teach a specific amount of glutamine, one of ordinary skill in the art would have been motivated to use the amounts of glutamine taught by Wadsworth et al and Klimberg et al. One would expect success because

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all three teach that glutamine treats stressed GI tracts by providing the essential fuel for intestinal immune cells (See, e.g. Shields, Jr. et al, col. 12, ln 11-22).

Shields, Jr. et al does teach the importance of antioxidants as scavengers of oxygen, and terminators of free radicals, and therefore their inclusion in the diet (col. 5, ln 65- col. 6, ln 11). Shields, Jr. et al, however, do not teach a specific amount of antioxidants present in the diet. Wadsworth et al also teach inclusion of vitamins and antioxidants, such as vitamins A and E, in amounts from 0-10% by weight (See Wadsworth et al; col. 5, ln 24-42). However, any pharmaceutical amount would be appropriate for these diets. Excess vitamins are flushed from the system; therefore, it would be obvious to include any amount of antioxidants, within a pharmaceutically accepted range, with expectations of the benefits and without concern of over dosage. Therefore, though Shields, Jr et al is silent on the amount of antioxidants in their diet, it would have been obvious to include any amount within a pharmaceutical range, such as 0.1-3% by weight.

Though Klimberg et al uses rats as the experimental animal, and Wadsworth et al dogs and cats, it would have been obvious to extend the results to include dogs, as described by Shields, Jr et al, because they are all mammals, dogs, cats and rats all have simple digestive tracts, and it is known that glutamine has similar beneficial effects on all three species, it is simply the amount of glutamine that is extrapolated from Klimberg et al and Wadsworth et al. For the same reasons it would be obvious to extend the results of Shields, Jr. et al, in view of Klimberg et al and Wadsworth et al, to include cats and other non-canine species, such as rats; therefore, a diet of the same composition, including glutamine, fermentable fiber, omega-3 fatty acids, and antioxidants in the specified amounts, and use of such composition for the management of diarrhea, would be obvious for use in dogs as well as non-canine mammals, such as cats and rats (Claims 1-15, 17, and 19). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

(b) Rejection of claims 1-15, 17 and 19 under 35 U.S.C. 103(a) over Chandler

Claims 1-15, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (*In Practice*, 2002).

Applicants claim 1 is directed to a composition suitable for oral ingestion by a mammal, comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3-fatty acid(s).

Dependent claims 2, 3 and 15 further define the mammal for which the composition must be suitable.

Dependent claims 4-13 further limit the quantity of each of the claimed components in the composition.

Applicants claim 14 is directed to a method for managing diarrhea in a mammal having GI tract inflammation, comprising orally administering the composition of claim 1. Dependent claim 17 further limits the type of mammal. Applicants claim 19 is directed to a method for managing diarrhea in a non-canine mammal, comprising orally administering to the mammal a composition comprising from about 0.1% to about 5% by weight glutamine, from about 0.5% to about 20% by weight fermentable fiber(s), from about 0.1% to about 3% by weight antioxidant(s), and from about 0.1% to about 3% by weight omega-3 fatty acid(s).

Chandler teaches diets for dogs and cats for the treatment and control of gastrointestinal diseases, which result in symptoms such as diarrhea. Chandler et al teach that a diet, which includes fermentable fibers, omega-3 fatty acids, antioxidants, and glutamine, can benefit an animal with a stressed gastrointestinal tract (See Chandler, Pg. 529, col. 2, and especially Pg. 533, col. 1). Chandler teaches a diet comprising these ingredients can be used as a treatment for gastrointestinal diseases (See Chandler, especially Pg. 533).

Though Chandler is silent on the precise amounts of glutamine, fermentable fibers, omega-3 fatty acids, and antioxidants, it would have been obvious to a person of ordinary skill in the art to experiment with varying amounts, within pharmaceutical ranges, of each ingredient to optimize the treatment

potential of the diet. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation.

Chandler teach that each specific ingredient plays an important role in maintaining and, in times of stress restoring gastrointestinal health (See Chandler, especially, Pg. 529, col. 1- Pg. 531, col. 1). A person of ordinary skill in the art would have been motivated to increase the amount of fermentable fiber, omega-3 fatty acids, and antioxidants, and to include glutamine in a diet for a dog or cat with GI tract problems because these ingredients are highly digestible, the fiber promotes fecal bulk, the omega-3 fatty acids help to decrease inflammation, antioxidants promote immune response, and need to be replaced during bouts of diarrhea due to being flushed out, and glutamine has been found to provide energy for enterocytes during times of stress, boosting immune ability and GI health (See Chandler, Pg. 529, col. 2- Pg. 533, col. 1). One would have expected success because Chandler describes a diet containing these ingredients as a means for treating GI problems (See Chandler, Pg. 529, col. 2- Pg. 533, col. 1) (Claims 1-15, 17, & 19). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

(10) Response to Argument

(a) The rejection of claims 1-15, 17 and 19 under 35 U.S.C. 103(a) over Shields, Jr. et al, in view of Klimberg et al and Wadsworth et al

(i) Arguments regarding claims 1-13

Regarding independent claim 1 applicants argue that, contrary to the cited references, their claims are directed to methods and compositions useful in ameliorating diarrhea caused by GI tract inflammation in a mammal; applicants argue the claimed composition comprises a specific combination of ingredients,

in specific amounts, which is not taught by the cited references. Applicants argue the cited references do not teach ameliorating the effects of inflammation, but rather teach compositions useful for other purposes, specifically rectifying immune deficiency (Shields, Jr. et al) and protection of intestinal mucosa from radiation-induced ulceration (Klimberg).

These arguments are not found persuasive. Initially it is noted that claims 1-13 (as well as claim 15) are directed to a composition, not a method of treating diarrhea; it has been held that if the body of claim fully and intrinsically sets forth all limitations of the claimed invention, such as all the components of a composition, and the preamble merely states the intended use of the invention, rather than any distinct definition of the any of the claimed invention's limitations, the preamble is not considered a limitation and is of no significance to claim construction. See MPEP § 2111.02. With regards to the make-up of the claimed composition, it is noted that the cited references, when viewed in combination, do teach or suggest each of the claimed components, in the specified amounts. Specifically: Shields, Jr. et al teach a composition comprising 4.0% fermentable fibers, 0.2% omega-3 fatty acids, antioxidants, and glutamine (See Shields, Jr. et al, col. 9, ln 48-51; col. 11, ln 25-38 & 53-54; col. 12, ln 11-15; col. 23, ln 4-14 & 'Analysis'); while Shields, Jr. et al is silent on the amounts of glutamine and antioxidants, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Klimberg et al and/or Wadsworth et al who teach mammalian diet compositions comprising 3% and 5-10% glutamine, respectively, the amount of antioxidants included in the diet would have been routinely optimized by one of ordinary skill in the art. Therefore, when viewed in combination, the cited references do, in fact, teach a composition comprising the claimed components, in the claimed concentrations, thereby rendering obvious the claimed composition.

Applicants further argue that there was no motivation to combine the cited references, any motivation to do so would have come from improper hindsight, "particularly since the cited references do

not suggest useful amounts of the ingredients" (Brief, Page 6, first full paragraph) and because the compositions taught by the cited art are preventative rather than ameliorating.

These arguments are not found persuasive. Improper hindsight was not relied upon to provide motivation to combine the cited references; the primary reference, Shields, Jr. et al, taught a particular diet composition that provides GI tract benefits, comprising each of the four ingredients claimed, but were silent as to the specific amounts of some of the components. In order to successfully produce the composition of Shields, Jr. et al, one of ordinary skill in the art would be motivated to look to the secondary references, Wadsworth et al and Klimberg et al, who each teach similar diet compositions, also disclosed as beneficial to the GI tract, as well as specific amounts of the glutamine component. It is further noted that, contrary to applicants statement, the cited references do each teach specific amounts of each of the ingredients, including specific amounts that fall within, or render obvious, the claimed ranges. Also, it is again pointed out that the claims are to a composition, not a method, therefore, applicant's argument that combination of the teachings would not be obvious because of different intended uses is not relevant.

(ii) Arguments regarding claim 15

Regarding dependent claim 15, which depends from claim 1, applicants argue that the primary reference, Shields, Jr. et al, discloses a breed specific dog food formulation; applicants argue there is nothing in the scope of the cited references that teaches or suggests the same formulation would be effective in non-canine animals.

This argument is not found persuasive. Initially it is again noted the claim is drawn to a composition, not an intended use of the composition, such as the species of animal to which it is to be administered; for the reasons discussed above the combination of references teaches the claimed composition, nothing in the claimed composition would render the composition unsuitable for non-canine

animals, as evidenced by the disclosures of Klimberg et al and Wadsworth et al, who each teach administering diets with the same ingredients to non-canine animals.

(iii) Arguments regarding claims 14 and 17

Regarding independent claim 14 and dependent claim 17, applicants argue the claims are directed to a method for managing diarrhea in a mammal having a GI tract inflammation, which they argue is not taught or suggested by the cited art. Applicants argue the cited references do not disclose anything relating to diarrhea. Applicants further argue that there is no motivation to combine the teachings of the cited references to achieve the claimed invention because the cited references cannot be combined.

These arguments are not found persuasive. In response to applicant's argument that the cited references do not teach managing diarrhea, or anything relating to diarrhea, it is noted that Shields, Jr. et al does, in fact, teach a diet comprising glutamine, fermentable fibers, omega-3-fatty acids, and antioxidants is intended to control GI inflammation and diarrhea (See Shields, Jr et al, col. 11, ln 18-28). Furthermore, each of the cited references teach that diets comprising the claimed components, particularly glutamine, are capable of improving gastrointestinal health. Specifically, Shields, Jr. et al teach that the glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See Shields, Jr et al, col. 12, ln 11-22); Wadsworth et al teach glutamine can provide improved digestive system support (See Wadsworth et al; col. 7, ln 51-60 and col. 13, ln 34-49 (Example 4)). Klimberg et al teach glutamine, when added to the diets of rats suffering gastrointestinal distress from abdominal radiation, diminished bloody diarrhea and reduced the incidence of bowel perforation (See Klimberg et al, Pg 1040, col. 2- Pg. 1041, col. 2). Diarrhea is a sign of diminished intestinal health (See Taber's Cyclopedic Medical Dictionary, 1997); therefore, administering the diets disclosed in the references to improve overall gastrointestinal health would inherently manage diarrhea.

Furthermore, it is noted that under the principles of inherency, if a prior art method, such as administration of the diets disclosed in the references, in their normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art method. When the prior art method is the same as a method described in the specification for carrying out the claimed method, it can be assumed the method will inherently perform the claimed process.

In response to applicant's argument that there was no motivation to combine the cited references, or an expectation of successfully doing so because the cited references cannot be combined, it is noted that applicants have provided no reasoning or support for why the references could not be combined. The secondary references are relied upon to extrapolate specific concentrations of ingredients, the examiner sees no reason why such information could not be extracted from one teachings and applied to another.

(iv) Arguments regarding claim 19

Regarding independent claim 19, applicants again argues that the cited reference do not teach a method for managing diarrhea in a non-canine animal because none of the references teach or suggest an invention relating to non-canine animals. Applicant's point out that Shields, Jr. et al is directed solely to canines; applicants argue there is no motivation to extend the teachings to non-canine animals.

This argument is not found persuasive. In response to applicant's argument that none of the references are directed to a method for managing diarrhea, as stated above, each of the cited references do deal with treatment of GI tract disorders, including diarrhea. In response to applicant's argument that it would not have been obvious to administer the composition to non-canine animals because none of the references relate to non-canine animals, it is noted that Wadsworth et al discusses both dogs and cats, and that Klimberg et al discusses rats; cats and rats are both non-canine animals. Furthermore, even though the primary reference, Shields, Jr. et al, focuses on canine diets, one of ordinary skill in the art would have

a reasonable expectation of successfully extrapolating the teachings to be applicable to other non-canine mammals, including cats and rats. Dogs, cats and rats have similar digestive systems, with a single stomach and a small colon; dogs and cats are even members of the same Order: Carnivora; there would be a reasonable expectation of similar activity within the digestive tracts of each one, especially in view of the teachings of the cited art, which disclose similar beneficial activity within each animal.

(b) The rejection of claims 1-15, 17 and 19 under 35 U.S.C. 103(a) over Chandler

(i) Arguments regarding claims 1-13

Regarding the composition of claims 1-13 being obvious over Chandler, applicants argue that Chandler does not teach or suggest the claimed ingredients in the specific concentration ranges claimed. Applicants argue that mere disclosure of the general principles is not sufficient to render obvious the claimed invention.

In response to applicants arguments that Chandler et al do not teach or disclose the claimed components in combination, or in the claimed concentrations, it is noted that Chandler et al teach that each of the claimed components are useful for treatment of gastrointestinal diseases that result in symptoms such as diarrhea. The motivation to combine the components taught by Chandler et al, each intended for the same purpose (treatment of stressed gastrointestinal tract) comes from the well established principle that it is *prima facie* obvious to combine two or more compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. Regarding the specific concentrations of each claimed component, the examiner maintains that it would have been well within the purview of one of ordinary skill in the art to routinely optimize the concentrations of each component taught by Chandler et al to arrive at the claimed composition. As stated previously, it is well established that differences in concentration will not support

the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Applicants have not provided any evidence that indicates the particular claimed ranges produce unexpected results.

(ii) Argument regarding claim 15

Regarding claim 15, which is dependent from claim 1, requiring the composition to be suitable for non-canine animals, applicants admit that Chandler discloses their nutritional information to be applicable to dogs and cats, but argues the information cannot be extrapolated to all non-canine mammals, as they particularly teach diets proven effective for certain conditions in humans have not been proven effective in dogs and cats.

In response, it is noted that cats are non-canine animals; therefore the teachings of Chandler do encompass non-canine animals. It is not required that the reference teach *all* non-canine animals.

(iii) Argument regarding claims 14 and 17

Regarding claims 14 and 17, directed to a method of managing diarrhea in a mammal, applicants argue that Chandler differs from the claimed invention in that they do not disclose anything relating to diarrhea.

In response to applicant's argument that Chandler does not disclose anything related to diarrhea, it is pointed out that Chandler specifically teach that a diet, which includes fermentable fibers, omega-3 fatty acids, antioxidants, and glutamine, can benefit an animal with a stressed gastrointestinal tract (See Pg. 529, col. 2, and especially Pg. 533, col. 1). Diarrhea is a symptom of various gastrointestinal diseases; including inflammatory bowel disease (See Taber's Cyclopedic Medical Dictionary, 1997); therefore, the disclosure of Chandler is related to management of diarrhea, as it focuses on management of diseases which report diarrhea as a symptom.

(iv) Argument regarding claim 19

Regarding independent claim 19, applicants again argue that Chandler does not teach a method for managing diarrhea in a non-canine animal because they do not teach a method relating to *all* canine animals.

In response, it is again noted that in order to render obvious a claim only one species included in the claimed genus is required, not *all*; therefore, because Chandler discusses applicability to dogs and cats, they do encompass at least one non-canine animal, and thus the rejection is proper.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

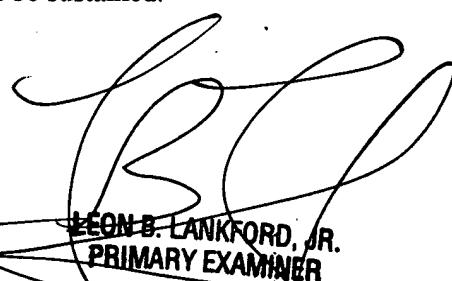
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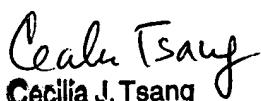
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